



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Meikle et al.

Application No.: 09/936,957

Filed: September 17, 2001

For: DIAGNOSIS OF LYSOMAL
STORAGE DISORDERS USING
SAPOSINS AND OTHER MARKERS

Examiner: Unassigned

Art Unit: 1641

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT UNDER 37
CFR §1.97 and §1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

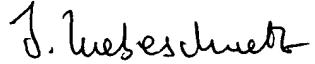
The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. Also enclosed is a copy of the International Search Report for the Corresponding PCT application. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

RECEIVED
TECH CENTER 1600/2900
JUL 31 2003

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Joe Liebeschuetz
Reg. No. 37,505

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 650-326-2422
JOL:crf
PA 3268046 v1

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Shee

1

of

2

Complete if Known

Application Number	09/936,957
Filing Date	September 17, 2001
First Named Inventor	Meikle
Art Unit	1641
Examiner Name	Unassigned
Attorney Docket Number	021385-014010US

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231
PA 3268046 v1

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

JUL 30 2003

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

of

2

Complete if Known

Application Number	09/936,957
Filing Date	September 17, 2001
First Named Inventor	Meikle
Art Unit	1641
Examiner Name	Unassigned

Attorney Docket Number

021385-014010US

RECEIVED
JUL 31 2003
TECH CENTER 1600
USPTO

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AC	ALEXANDER et al., "5 Related Lebanese Individuals with high Plasma Lysosomal Hydrolases A New Defect in Mannose-6-Phosphate Receptor Recognition," <u>Am. J. Human Genetics</u> , 36(5):1001-1014 (1984).	
	AD	BROOKS et al., "Immunoquantification of the Low Abundance Lysosomal Enzyme N-acetylgalactosamine 4-sulphatase," <u>J. Inherited Metabolic Disease</u> , 13(1):108-120 (1990).	
	AE	GATTI et al., "Comparative Study of 15 Lysosomal Enzymes in Chorionic Villi and Cultured Amniotic Fluid Cells. Early Prenatal Diagnosis in Seven Pregnancies at Risk for Lysosomal Storage Diseases," <u>Prenatal Diagnosis</u> , 5(5):329-336 (1985).	
	AF	GRIFFITHS et al., "Plasma Acid Hydrolases in Normal Adults and Children, and in Patients with Some Lysosomal Storage Diseases," <u>Clinical Chimica Acta: Int. J. of Clinical Chemistry</u> , 90(2):129-141 (1978).	
	AG	HUA et al., "Evaluation of the Lysosome-Associated Membrane Protein LAMP-2 as a Marker for Lysosomal Storage Disorders," <u>Clinical Chemistry</u> , 44(10):2094-2102 (1998).	
	AH	KLEIMAN et al., "Sandhoff Disease in Argentina: High Frequency of a Splice Site Mutation in the HEXB Gene and Correlation Between Enzyme and DNA-Based Tests for Heterozygote Detection," <u>Human Genetics</u> , 94:279-282 (1994).	
	AI	LOVELL et al., "Biochemical and Histochemical Analysis of lysosomal Enzyme Activities in Caprine Beta-Mannosidosis," <u>Molecular and Chemical Neuropathology</u> , 21(1):61-74 (1994).	
	AJ	McCABE et al., "Preferential Inhibition of Lysosomal Beta Mannosidase by Sucrose," <u>Enzyme</u> , 43(3):137-145 (1990).	
	AK	O'BRIAN et al., "Saposin proteins: structure, function, and role in human lysosomal disorders," <u>FASEB J.</u> , 5(3):301-308 (1991).	
	AL	PRENCE et al., "Diagnosis of Alpha Mannosidosis by Measuring Alpha Mannosidase in Plasma," <u>Clinical Chemistry</u> , 38(4):501-503 (1992).	
	AM	TAGER, J.M., "Biosynthesis and deficiency of lysosomal enzymes," <u>TIBS</u> , 10(8):324-326 (1985)	
	AN	WHITLEY et al., "Long-term Outcome of Hurler Syndrome Following Bone Marrow Transplantation," <u>Am. J. Medical Genetics</u> , 46(2):209-218 (1993).	
	AO	YAMAGUCHI et al., "Improvement of Tear Lysosomal Enzyme Levels After Treatment with Bone Marrow Transplantation in a Patient with I-Cell Disease," <u>Ophthalmic Research</u> , 21(3):226-229 (1989).	
	AP	YUFENG et al., "Elevated Plasma Chitotriosidase Activity In Various Lysosomal Storage Disorders," <u>J. Inherited Metabolic Disease</u> , 18(6):717-722 (1995).	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PA 3268046 v1

Please type a plus sign (+) inside this box →

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL
FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

5

Application Number

09/936,957

Filing Date

09/17/2001

First Named Inventor

Meikle

Group Art Unit

1641

Examiner Name

Unassigned

RECEIVED
TECH CENTER 1641
JUL 31 2003

Attorney Docket Number

021385-014010US

ENCLOSURES (check all that apply)

 Fee Transmittal Form Assignment Papers
(for an Application) After Allowance Communication to Group Fee Attached Drawing(s) Appeal Communication to Board of Appeals and Interferences Amendment / Response Licensing-related Papers Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) After Final Petition Routing Slip (PTO/SB/69) and Accompanying Petition Proprietary Information Affidavits/declaration(s) Petition to Convert to a Provisional Application Status Letter Extension of Time Request Power of Attorney, Revocation Change of Correspondence Address Other Enclosure(s)
(please identify below): Express Abandonment Request Terminal Disclaimer

1) Sixteen (16) cited references

 Information Disclosure Statement Request for Refund

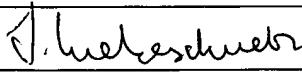
2) Return receipt postcard

 Certified Copy of Priority Document(s) CD, Number of CD(s)

3) INTERNATIONAL SEARCH REPORT

 Response to Missing Parts/ Incomplete ApplicationRemarks
The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430. Response to Missing Parts under 37 CFR 1.52 or 1.53Total number of pages does not include cited references.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Joe Liebeschuetz	
Signature		
Date	July 9, 2003	

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date:

July 9, 2003

Typed or printed name	Chris Fitting
Signature	
Date	July 9, 2003

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PA 3309111 v1